510(k) Summary for Dimension Vista™ B2MIC Flex® reagent cartridge Dimension Vista™ Protein 1 Calibrator Dimension Vista™ Protein 1 Control M and H

JAN 2 6 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K063272

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:
Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
35001 Marburg, Germany

Contact Information:
Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: October 27, 2006

2. Device Name:
Dimension Vista™ B2MIC Flex® reagent cartridge
Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Control M
Dimension Vista™ Protein 1 Control H

Classification: Class II; Class II; Class I
Product Code: JZG; JIX; JJY
Panel: Immunology (82) and Clinical Chemistry (75)

3. Identification of the Legally Marketed Device:

Dade Behring N Latex β_2-Microglobulin – K002731
Dade Behring N Protein Standard SL – K012470
Dade Behring N/T Protein Control SL – K012468

4. Device Description:

Dimension Vista™ B2MIC Flex® reagent cartridge
Polystyrene particles coated with specific antibodies to human β_2-microglobulin are aggregated when mixed with samples containing human β_2-microglobulin. These aggregates scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

Dimension Vista™ Protein 1 Calibrator
Protein 1 Calibrator is a multi-analyte, liquid, human serum based product containing β_2-microglobulin C3 complement, C4 complement, immunoglobulin A (IGA), immunoglobulin G (IGG), immunoglobulin M (IGM), and prealbumin / transthyretin (PREALB).

Dimension Vista™ Protein 1 Control M and H
Protein 1 Control M and H are multi-analyte, liquid, human serum based products containing β_2-microglobulin C3 complement, C4 complement, immunoglobulin A (IGA), immunoglobulin G (IGG), immunoglobulin M (IGM), and prealbumin / transthyretin (PREALB).

5. Device Intended Use:

Dimension Vista™ B2MIC Flex® reagent cartridge:
The B2MIC method is an *in vitro* diagnostic test for the quantitative determination of β_2-microglobulin in human serum, or heparinized or EDTA plasma on the Dimension Vista® System. Measuresments of β_2-microglobulin aid in the diagnosis of renal dysfunction.

Dimension Vista™ Protein 1 Calibrator:
PROT1 CAL is an *in vitro* diagnostic product for the calibration of the β_2-microglobulin (B2MIC), C3 complement (C3), C4 complement (C4), Immunoglobulin A (IGA), Immunoglobulin G (IGG), Immunoglobulin M (IGM) and Prealbumin / Transthyretin (PREALB) methods on the Dimension Vista® System.

Dimension Vista™ Protein 1 Control M and H:
PROT1 CON M and H are assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of β_2-microglobulin (B2MIC), C3 Complement (C3), C4 Complement (C4), immunoglobulin A (IGA), immunoglobulin G (IGG), immunoglobulin M (IGM) and prealbumin / transthyretin (PREALB) on the Dimension Vista® System.

6. Medical device to which equivalence is claimed and comparison information:

The Dimension Vista™ B2MIC Flex® reagent cartridge, Dimension Vista™ Protein 1 Calibrator and Dimension Vista™ Protein 1 Control M and H are substantially equivalent to the Dade Behring N Latex β_2-Microglobulin assay (K002731), N Protein Standard SL (K012470), and N/T Protein Control SL (K012468), respectively.

7. Device Performance Characteristics:

The Dimension Vista™ B2MIC assay was compared to the Dade Behring N Latex β_2-Microglobulin assay on the BN ProSpec® System by evaluating serum and plasma samples with concentrations ranging from 0.81 to 21.94 mg/L. Regression analysis of these results yielded the following equation:

Method Comparison Study

Comparative Method	n	Slope	Intercept	Correlation Coefficient
N Latex β_2-Microglobulin on BN ProSpec® System	143	0.942	-0.029	0.998

8. Conclusion:

These studies demonstrate correlation and equivalent performance between the Dade Behring N Latex β_2-Microglobulin assay and the Dimension Vista™ B2MIC assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dade Behring Inc.
c/o Ms. Kathleen Dray-Lyons
Regulatory Affairs and Compliance Manager
Glasgow Site
P.O. Box 6101
Newark, DE 19714-6101

JAN 26 2007

Re: k063272
Trade/Device Name: Dimension Vista™ B2MIC Flex® reagent cartridge
Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Control M
Dimension Vista™ Protein 1 Control H
Regulation Number: 21 CFR 866.5630
Regulation Name: Beta-2-Microglobulin Immunological Test System
Regulatory Class: Class II
Product Code: JZG, JIX, JJY
Dated: December 20, 2006
Received: December 26, 2006

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications Statement

K063272

Device Name: **Dimension Vista™ B2MIC Flex® reagent cartridge**
Dimension Vista™ Protein 1 Calibrator
Dimension Vista™ Protein 1 Control M
Dimension Vista™ Protein 1 Control H

Indications for Use:

Dimension Vista™ B2MIC Flex® reagent cartridge:
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Dimension Vista™ Protein 1 Calibrator
PROT1 CAL is an *in vitro* diagnostic product for the calibration of the β_2-microglobulin (B2MIC), C3 Complement (C3), C4 Complement (C4), Immunoglobulin A (IGA), Immunoglobulin G (IGG), Immunoglobulin M (IGM) and Prealbumin / Transthyretin (PREALB) methods on the Dimension Vista® System.

Dimension Vista™ Protein 1 Control M and H
PROT1 CON M and H are assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of β_2-microglobulin (B2MIC), C3 Complement (C3), C4 Complement (C4), immunoglobulin A (IGA), immunoglobulin G (IGG), immunoglobulin M (IGM) and prealbumin / transthyretin (PREALB) on the Dimension Vista® System.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D)
Over-The-Counter-Use_____ (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

(Optional) 063272